

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



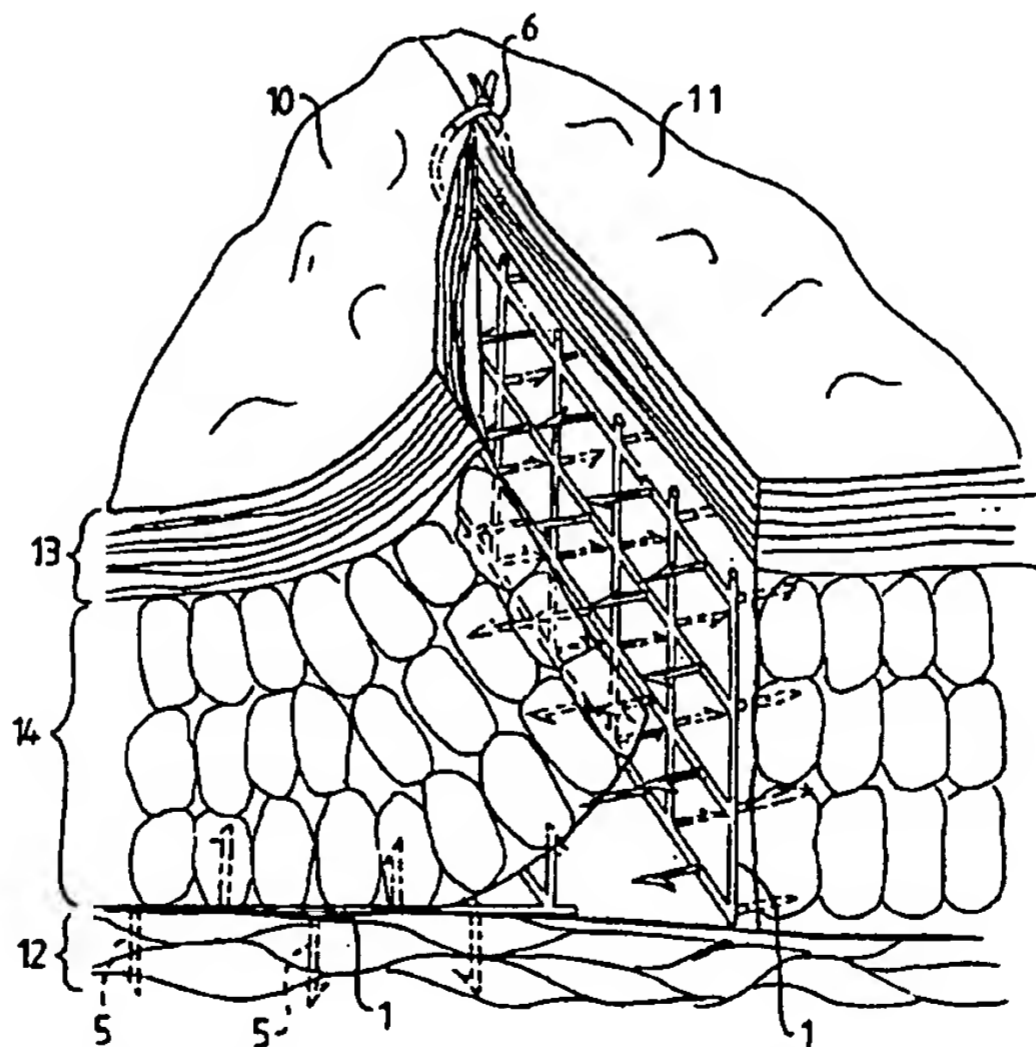
(43) International Publication Date  
9 August 2001 (09.08.2001)

PCT

(10) International Publication Number  
**WO 01/56477 A2**

- (51) International Patent Classification<sup>7</sup>: A61B 17/04 (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZW.
- (21) International Application Number: PCT/ZA01/00013
- (22) International Filing Date: 6 February 2001 (06.02.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
2000/0539 7 February 2000 (07.02.2000) ZA
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- (71) Applicant and  
(72) Inventor: ASH, Gregory, John [ZA/ZA]; Suite 8, 3rd floor, Umhlanga Hospital, Umhlanga Drive, 4320 Umhlanga (ZA).
- Published:  
— without international search report and to be republished upon receipt of that report
- (74) Agent: TRUTER, Jacobus, Tridoux; D M Kisch INC, P.O. Box 781218, 2146 Sandton (ZA).
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DEVICE FOR USE IN SURGERY



(57) Abstract: The invention provides a device suitable for use in surgery to facilitate closure of a surgical or traumatic wound, the device comprising a support structure extending generally in a first plane and at least one pin formation on either side of the support structure which pin formations are secured to the support structure to extend transversely to the plane of the support structure, and wherein at least one of the pin formations features at least one bar structure at or near its free end. The invention also provides a surgical method of closure of a wound involving the use of a device according to the invention.

WO 01/56477 A2

**FIELD OF THE INVENTION****DEVICE FOR USE IN SURGERY**

**THIS** invention relates to a device for use in surgical procedures.

More particularly, this invention relates to the device useful in achieving, or  
5 at least approaching, precise coaption of the deeper [fat] layer of a surgical  
wound during a surgical wound closure procedure, thereby to enhance the  
prospect of achieving rapid wound healing without complications. The  
device is also intended to assist the surgeon in performing the procedures  
necessary for achieving such a wound closure in a reasonable time, and not  
10 unduly to prolong the duration of the patient's anaesthesia in seeking to  
achieve this goal.

**BACKGROUND TO THE INVENTION**

When stitching up a surgical incision made through, say, the abdominal wall  
15 of a patient, it is necessary first to stitch together the abutting muscle  
segments of the abdominal wall, and then to join the opposing skin  
segments by stitching. The fat layer disposed between the skin and the  
muscular abdominal wall has a consistency similar to that of butter or  
cheese. It accordingly presents no, or, at best, very little anchorage for the  
20 sutures, and cannot reasonably be sutured together. If sutured with  
conventional techniques fat enclosed by the suture has diminished blood  
supply and often dies and is thus at risk for infection or excessive scar  
formation. In an attempt to bring and hold the interposed fat layers on

either side of the incision in contact to enable these to reunite, it is customary to pass large sutures through both the skin and the muscle layers so as to hold the fat passively and indirectly together. In slim people with a thin layer of fat, and thus where skin and muscle sutures are close to each other, this may be effective in keeping fat layers closely abutting to allow healing. There does, however, remain a potential space in the plane of the fat. In obese people in particular, the fat layers may recede from each other creating what is referred to as a "*dead space*".

10 Serum and/or blood are prone to collect in this space with the attendant danger of infection. This retraction of the fat layer may also lead to indented scars.

In addition, it is common, particularly in plastic surgery to perform surgical procedures in which large sections of skin and fat are undermined and removed or moved. One such procedure is known as abdominoplasty, colloquially known as the "*tummy tuck*" procedure. In this procedure an incision extending virtually from hipbone to hipbone is made just above the pubic area to extend through the skin and underlying fat layer. The skin and fat layer is then undermined from the underlying muscular abdominal wall to reveal the muscles of the abdomen up to the ribcage. The vertical muscles [rectus abdominis] are thereupon stitched close together to provide the patient with a reduced waistline and a firmer abdominal wall. The

undermined skin and fat flap is then stretched over the tightened abdominal wall and joined by stitching to the edge of the incision made above the pubic area after excess skin and fat has been trimmed from the flap. It is technically difficult if not impossible to suture the overlying fat onto the underlying muscles, both because of the nature of the fat mentioned above and because the flap itself blocks access. Furthermore, the alignment of the flap over muscles is difficult to maintain while trying to pass a suture. Lateral movement is therefore possible between skin/fat flap and muscles and a huge potential space exists which commonly leads to complications because of the collection of blood [haematoma] or serum [seroma]. This occurs despite drainage of the space, which is universally practised. This is one of the major causes of the need for corrective surgical procedures, or other treatment following abdominoplasty and other surgical procedures in which large parts of skin and fat are separated from the underlying muscle.

15

#### **DESCRIPTION OF THE INVENTION**

According to the present invention there is provided a device suitable for use in surgery to facilitate closure of a surgical wound, the device comprising a support structure extending generally in a first plane and at least one pin formation on either side of the support structure which pin formations are secured to the support structure to extend transversely to the plane of the support structure, and wherein at least one of the pin formations features at least one barb structure at or near its free end.

20

The support structure may be in the form of a thin plate. Thus the support structure may be of circular, elliptical, rectangular, square, triangular or any other convenient shape. From the opposing surfaces of the plate there  
5 extends a barbed pin or a plurality of barbed pins. The barbed pins preferably extend normally to the surface of the plated support structure.

In an alternative form of the invention the support structure may comprise a rod formation with barbed pins extending transversely from the rod  
10 formation. In this arrangement the barbed pins may be disposed in twinned pairs on opposite sides of the rod formation and along the length thereof. The barbed pins are however preferably alternatingly disposed along the length to extend away from the rod formation at intervals along the length thereof and to be disposed in a common plane with the rod structure.

15

In yet a further alternative arrangement according to the invention there is provided a device according to the invention in which the support formation is in the form of a lattice structure composed of a plurality of rod-like elements which are arranged in two sets of elements which intersect one  
20 another. The two sets of intersecting elements may each comprise a plurality of elements which extend parallel to each other. Preferably the support structure comprises two sets of parallel rod structures, the elements of which sets intersect one another at any suitable angle. Thus, the two sets

of rod-like structures may intersect one another at right angles and the rods may all be equidistantly spaced thereby to define a lattice structure featuring substantially square interstices. The sets of parallel rod-like structures may, however, also intersect one another at an angle, thereby to define a lattice  
5 structure featuring diamond-shaped interstices.

The lattice structure may be formed as a unitary structure. Alternatively, however, it may be manufactured in sets of two configurations of elements which are capable in use to be integrated with one another to form a lattice  
10 structure of desired size.

In this form of the invention the device may thus be a composite device made up of a plurality of elongate apertured plates, as first elements, and, as second elements, a plurality of pins extending transversely thereto to be  
15 disposed in a plane which also contains the rod, the arrangement being such that in use the pins of the rod elements may be passed through the apertures in the plate elements to be firmly engaged therein, thereby to form a sturdy lattice structure substantially disposed in the plane of the rod structures and featuring pins extending through the plate elements in a  
20 direction normal to that plane.

In all these lattice-type structures, and in the embodiment of the invention comprising a single rod as a support structure, the rod-like structures may be

of any suitable cross-sectional configuration but are preferably round, rectangular or elliptical in cross-sectional configuration.

The device according to the invention may be produced from any suitable  
5 biocompatible material. Preferably, this material should be slowly absorbable  
*in vivo*. Many examples of such materials are known. Natural polymers  
falling in this category include catgut, cellulose derivatives and collagen.  
Synthetic polymers may, for example, consist of various aliphatic polyesters.  
In U.S. Patent 5,633,343 there is a disclosure of such a biocompatible,  
10 absorbable copolymer. That specification also discloses numerous other U.S.  
patents relating to such absorbable polymeric materials which may be useful  
in the production of a device in accordance with the present invention. One  
suitable material is the polyglycolic acid polymer used in the production of  
sutures sold by Ethicon Inc. under the trade name Monocryl®.

15

The dimensions of the device may vary according to its application. When to  
be used where the soft tissues are thin the pins may be only a millimetre or  
less in length and obviously only a few micrometers thick. For use in  
abdominal surgery the pins may be of a length measured in centimetres.  
20 The device may in use be cut by means of scissors to appropriate dimensions  
and the rods may thus be provided with a weakened zone to facilitate  
reducing a sheet of the product to an appropriate dimension.

**EXAMPLES OF THE INVENTION**

Without thereby limiting the scope of the present invention, a preferred embodiment will now be described with reference to the accompanying illustrations in which:

5

Figure 1 is a schematic perspective view of a lattice device according to the present invention;

Figure 2 a cross-sectional view on line II-II in Figure 1;

Figure 3 is a schematic perspective cross-sectional view through a surgical wound being stitched up with the utilisation of a device as illustrated in Figure 1;

10

Figure 4 is a perspective view of a composite second embodiment of the invention in assembled form;

15

Figure 5 is an elevational view of a segment of a first element of a composite second embodiment of the device of the invention of Figure 4; and

Figure 6 is an elevational view of a segment of a segment of a second element of the composite second embodiment of the invention of Figure 4.

20

The same reference numerals are used in the accompanying drawings to signify corresponding parts.

In Figure 1 there is illustrated a lattice device 1 composed of intersecting sets of rod structures 2, 3 which are respectively disposed in parallel relationship relative to one another. Collectively they define a latticework with square interstices 4. Barbed pins or pins 5 extend normally to the  
5 lattice structure defined by the rod structures. The arrangements of the barbed pins are shown to be alternating, i.e. not to be coaxially disposed on opposite sides of the plane of the lattice structure so as to allow or the surgeon to apply pressure in the direction of the axis of individual or rows of the barbed pins or pins.

10

With reference now to the illustration of Figure 3, a skin flap indicated by numeral 10, such as the flap resulting from the procedure known as abdominoplasty, is shown to be joined to the remaining skin left during the procedure at the pubic area 11. First a device as shown in Figure 1 is placed  
15 on the muscular layer of the abdominal wall of the patient and pressure is applied to the lattice structure to cause the pins 5 to penetrate into the muscular layer 12 of the abdominal wall. Thereupon the skin flap 10 is lowered onto the abdominal wall which now features the barbed pin device. Pressure is applied on the skin surface to cause the pins to penetrate into the  
20 fat layer beneath the skin. Being so anchor the skin flap 10 has a reduced tendency to withdraw from the edge of the incision at the pubic area of the patient and lateral movement of the skin/flat flap relative to the muscles when the patient moves will be reduced almost to zero. This will close the

dead space and facilitate rapid healing of the flap onto the underlying muscles. To further facilitate the wound closure a further section of the device illustrated in figure 1 is placed between the wound edges to be joined together. Again slight pressure may be applied to the device to cause the  
5 pins 5 to penetrate into the fat layer on either side of the wound to be closed. Small stitches 6 passing through and below the skin layer 13 may now be used to suture the skin edges together. Pressure may beforehand be applied at an angle to the surface of the skin and directed at the surfaces of the fat layer 14 of the incision or wound to be closed to ensure proper  
10 penetration of the pins of the device into the fat layer 14 to prevent subsequent recession of these surfaces, at least to the degree experienced when stitching is performed without the device of the invention.

Turning now to the arrangement set out in Figures 4 to 6, the surgical device  
15 is shown to comprise a number of elongate plate members 15 which are disposed in parallel relationship to one another, and a plurality of pinned rod elements of square cross-sectional configuration 16, also extending parallel to one another.

20 The rod elements 16 feature transversely extending pins 17 and 18 and those pins each feature a number of barbs 17(a) and 18(a).

The pins 17 or 18 are passed through apertures 19 provided in the plate elements 15.

The dimensional configuration of the pins 17 and 18 and the apertures is  
5 such that in use the pins are snugly received through the aperture to be securely frictionally engaged therein. If desired the shaft of the pin may include a recessed zone to allow for it to be clipped into the aperture and be retained by a shoulder of the recessed zone which is not shown in the drawings.

10

Since the device is produced from biocompatible material it will not need to be removed after the operation. In the preferred embodiment it will be bioabsorbable and so will simply be absorbed by the body.

15 Clearly many variations of the invention may be devised without thereby departing from the spirit of the invention. It is anticipated that the pins may be set at an acute angle to the plane of the lattice structure and opposing pins may be co-axially mounted, if desired.

**CLAIMS**

1. A device suitable for use in surgery to facilitate closure of a surgical wound, the device comprising a support structure extending generally  
5 in a first plane and at least one pin formation on either side of the support structure which pin formations are secured to the support structure to extend transversely to the plane of the support structure, and wherein at least one of the pin formations features at least one barb structure at or near its free end.  
10
2. The device of claim 1 wherein the support structure is in the form of a thin plate from the opposing surfaces of which there extend a plurality of barbed pins, which preferably extend normally to the surface of the support structure.  
15
3. The device of claim 1 wherein the support structure comprises a rod formation with barbed pins extending transversely from the rod formation, the barbed pins being disposed in twinned pairs on opposite sides of the rod formation and along the length thereof.  
20
4. The device of claim 1 wherein the support formation is in the form of a lattice structure composed of a plurality of rod-like elements which are arranged in two sets of elements which intersect one another, the

two sets of intersecting elements each comprising a plurality of elements which extend parallel to each other.

- 5 5. The device of claim 4 wherein the support structure comprises two sets of parallel rod structures, the elements of which sets preferably intersect one another at right angles and wherein the rods are preferably equidistantly spaced thereby to define a lattice structure featuring substantially square interstices.
- 10 6. The device of claim 4 or 5 wherein the lattice structure is formed as a set of two configurations of elements which are capable in use to be integrated with one another to form a lattice structure of desired size.
- 15 7. The device of claim 6 which is a composite device made up of a plurality of elongate apertured plates, as first elements, and, as second elements, a plurality of pins extending transversely thereto to be disposed in a plane which also contains the rod, the arrangement being such that in use the pins of the rod elements may be passed through the apertures in the plate elements to be firmly engaged  
20 therein, thereby to form a sturdy lattice structure substantially disposed in the plane of the rod structures and featuring pins extending through the plate elements in a direction normal to that plane.

8. The device of any one of claims 3 to 7 wherein the rod-like structures are preferably of round, rectangular or elliptical in cross-sectional configuration.
- 5
9. The device of claim 1 produced from a biocompatible material, preferably, a material which is slowly absorbable *in vivo* and is most preferably polyglycolic acid polymer.
- 10 10. A method of disclosure of a wound which includes the step of inserting a device as claimed in any one of claims 1 to 9 into the wound.

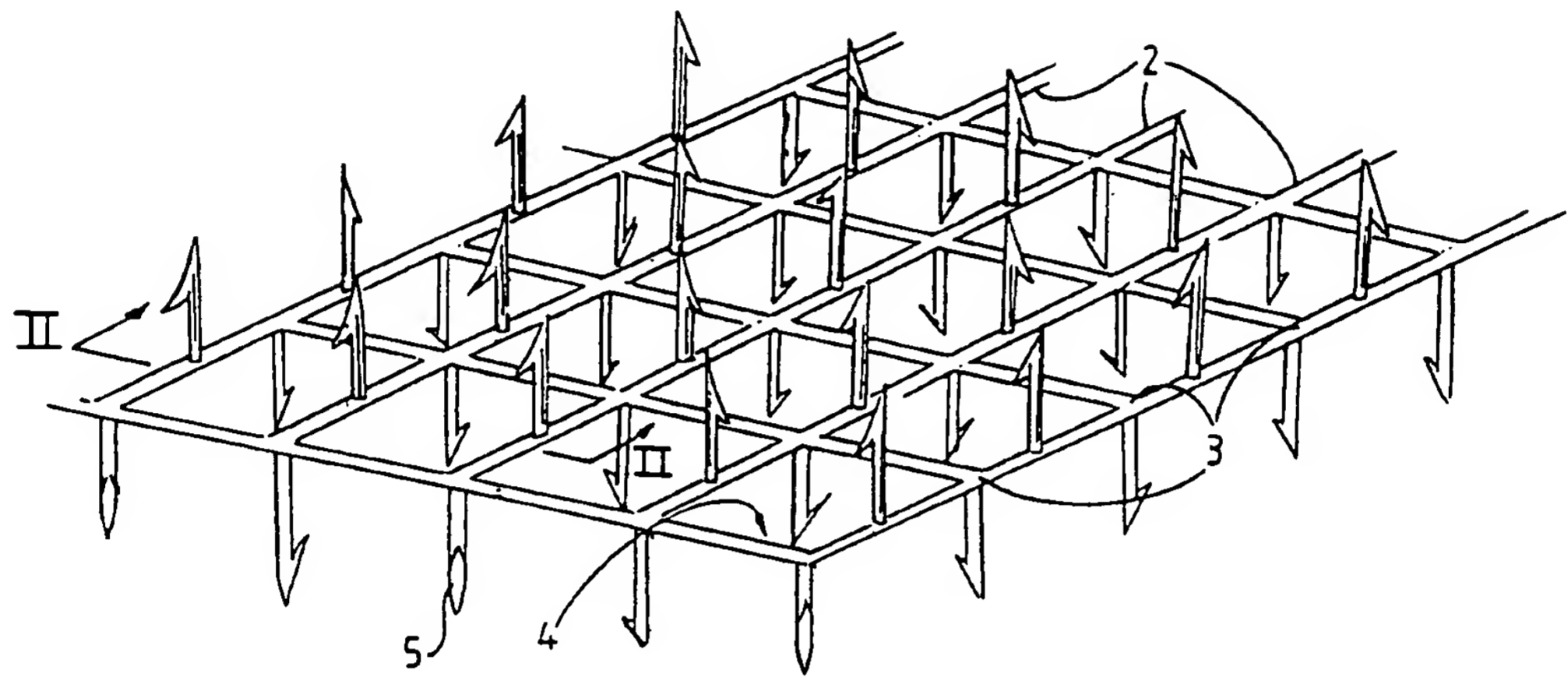


FIGURE 1

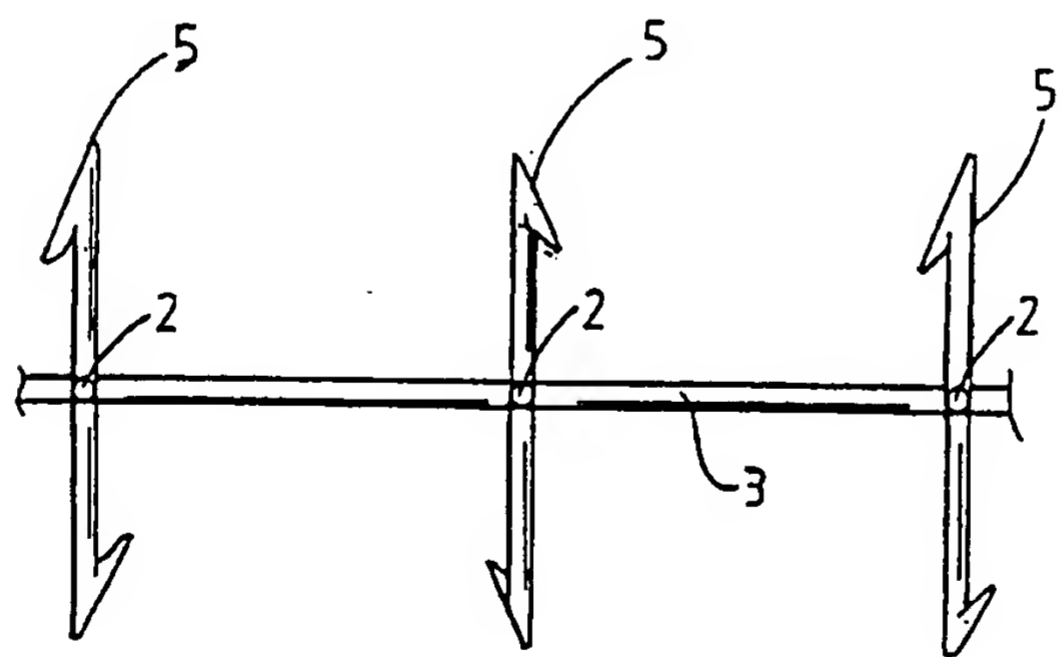


FIGURE 2

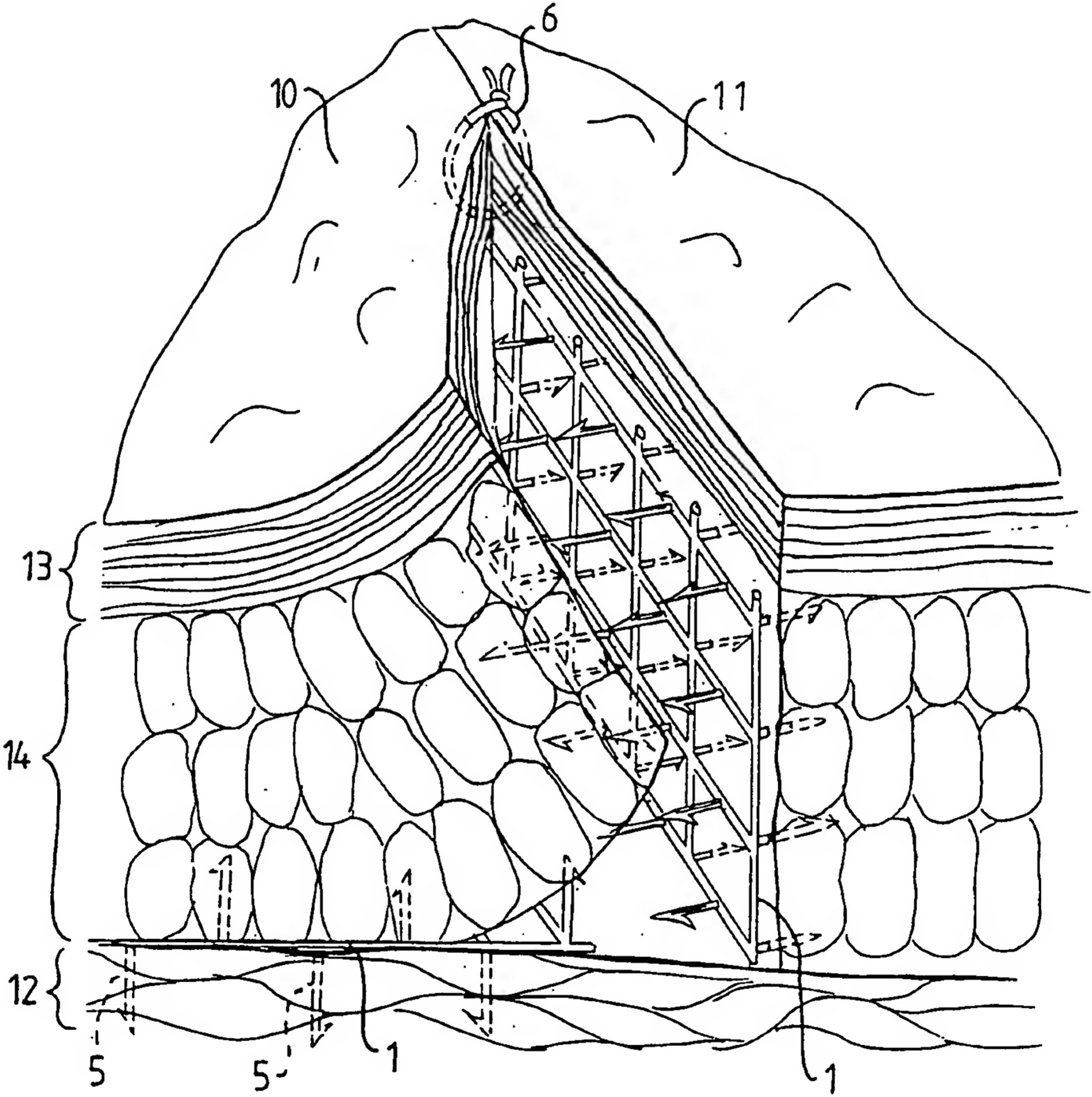


FIGURE 3

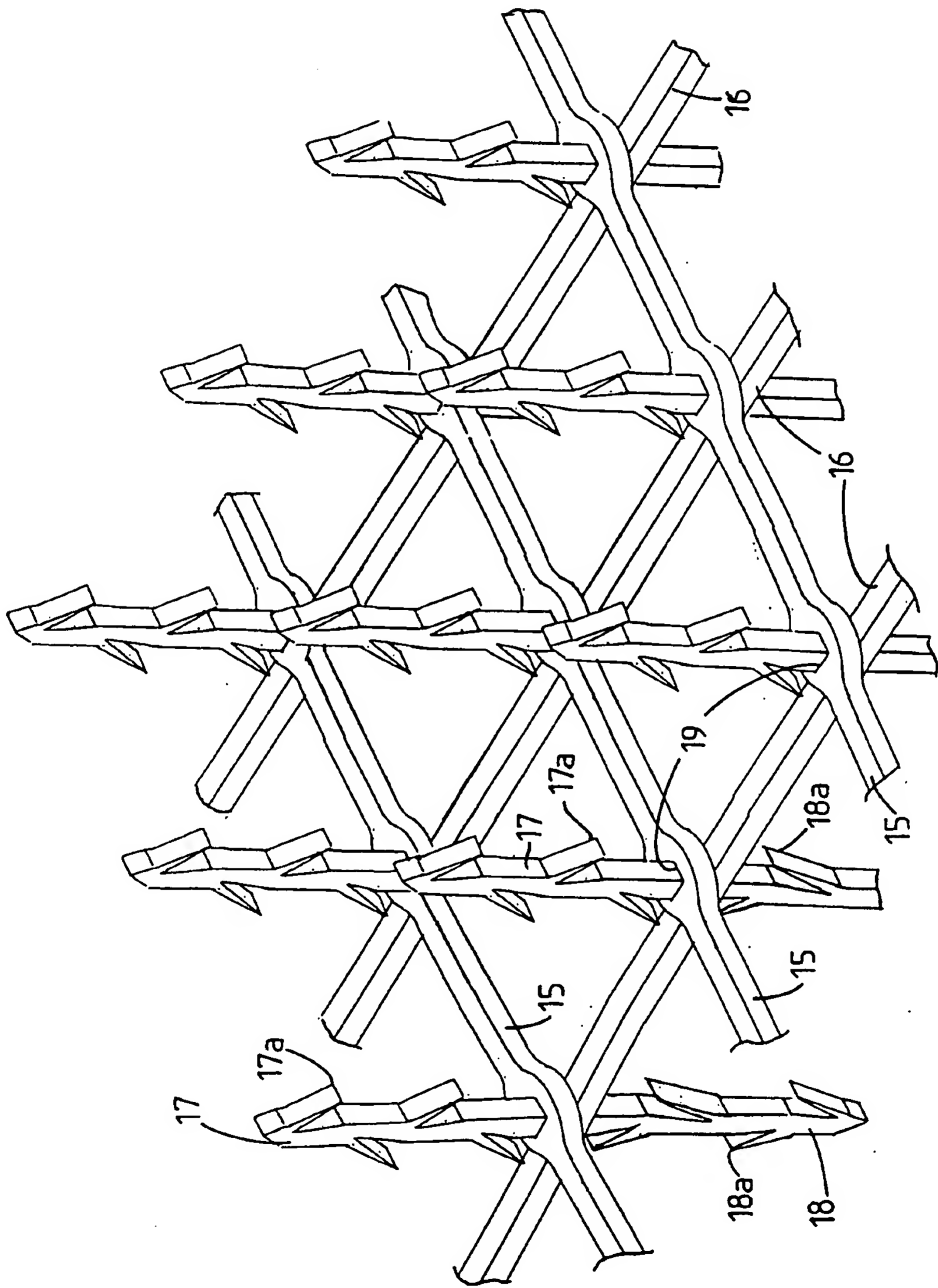


FIGURE 4

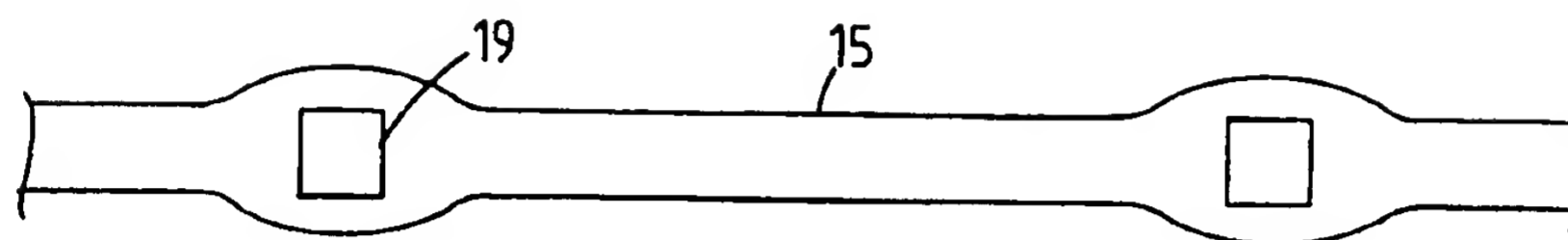


FIGURE 5

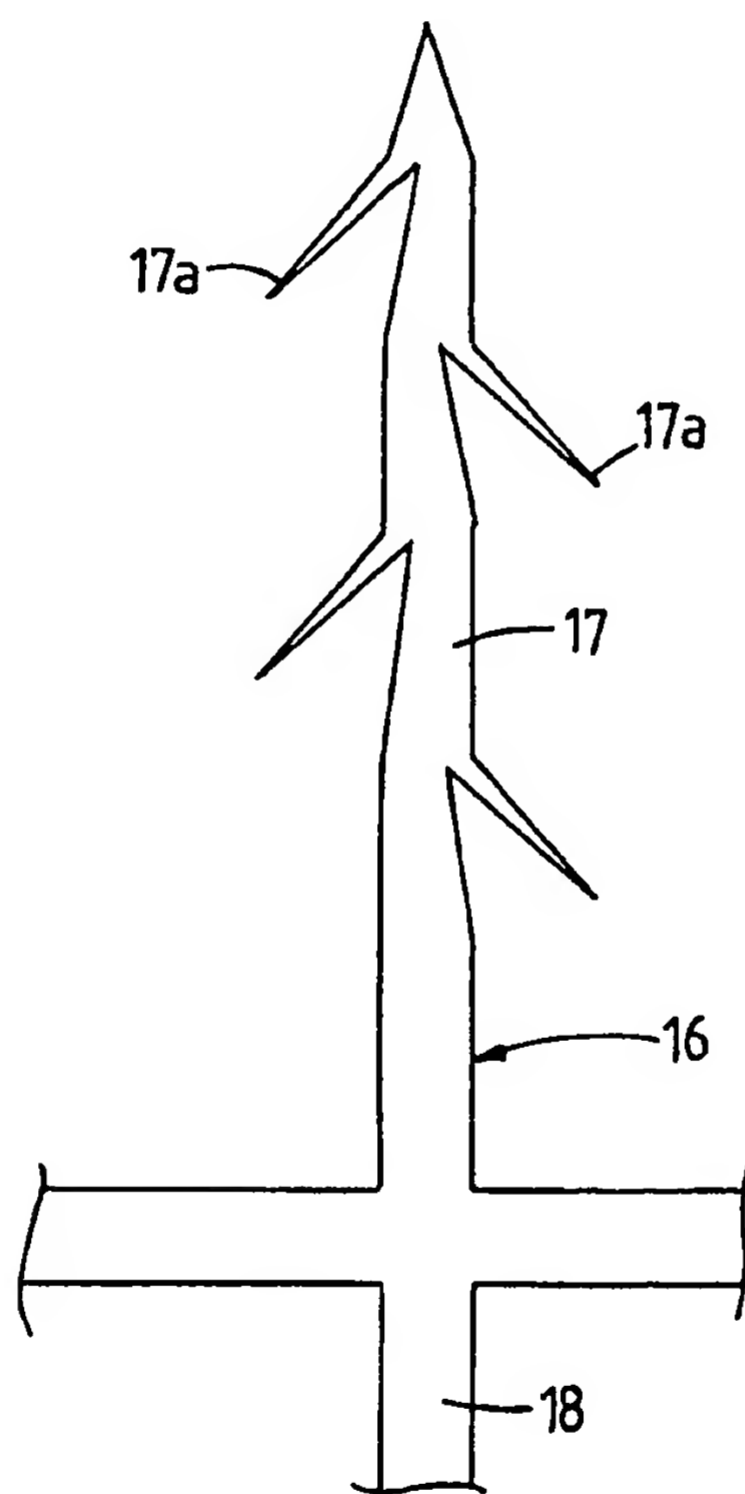


FIGURE 6

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
9 August 2001 (09.08.2001)

PCT

(10) International Publication Number  
**WO 01/56477 A3**

(51) International Patent Classification<sup>7</sup>: **A61B 17/04**,  
17/08

(21) International Application Number: PCT/ZA01/00013

(22) International Filing Date: 6 February 2001 (06.02.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
2000/0539 7 February 2000 (07.02.2000) ZA

(71) Applicant and  
(72) Inventor: **ASH, Gregory, John [ZA/ZA]**; Suite 8, 3rd  
floor, Umhlanga Hospital, Umhlanga Drive, 4320 Umh-  
langa (ZA).

(74) Agent: **TRUTER, Jacobus, Tridoux: D M Kisch INC.**  
P.O. Box 781218, 2146 Sandton (ZA).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ,

DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,  
HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,  
LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ,  
NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,  
TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian  
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European  
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,  
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,  
CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

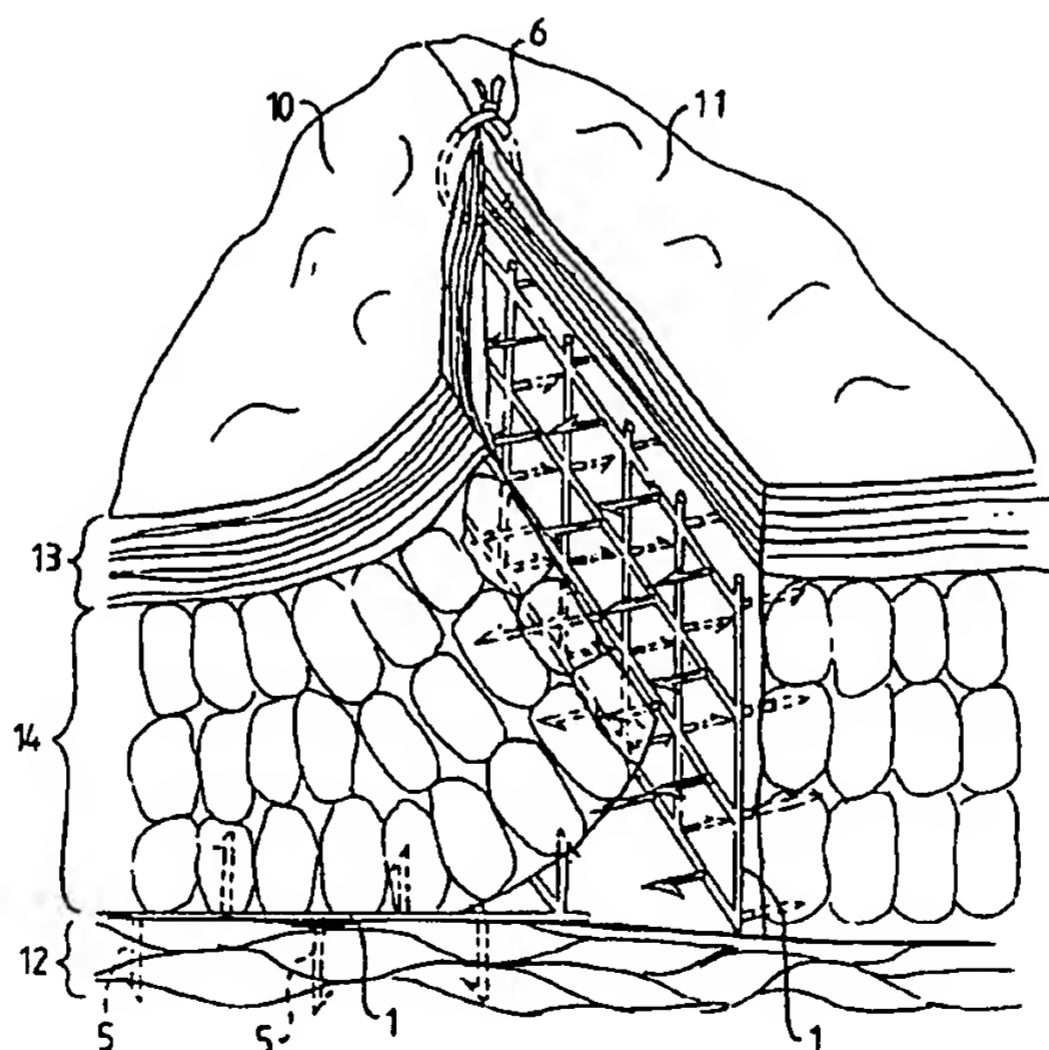
Published:

— with international search report

(88) Date of publication of the international search report:  
31 January 2002

For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

(54) Title: **DEVICE FOR FACILITATING CLOSURE OF A SURGICAL WOUND**



(57) Abstract: The invention provides a device suitable for use in surgery to facilitate closure of a surgical or traumatic wound, the device comprising a support structure extending generally in a first plane and at least one pin formation on either side of the support structure which pin formations are secured to the support structure to extend transversely to the plane of the support structure, and wherein at least one of the pin formations features at least one bar structure at or near its free end. The invention also provides a surgical method of closure of a wound involving the use of a device according to the invention.

WO 01/56477 A3

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/ZA 01/00013

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/04 A61B17/08

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 425 747 A (BROTZ GREGORY R) 20 June 1995 (1995-06-20) abstract; figure 2 ---	1-9
A	US 5 584 859 A (BROTZ GREGORY R) 17 December 1996 (1996-12-17) abstract; figure 2 ---	1-9
A	US 5 843 125 A (JEMPOLSKY LAWRENCE) 1 December 1998 (1998-12-01) abstract; figure 1 ---	1-9
A	US 5 047 047 A (YOON INBAE) 10 September 1991 (1991-09-10) abstract; figures 1,2 -----	1-9

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*Z\* document member of the same patent family

Date of the actual completion of the international search

21 September 2001

Date of mailing of the international search report

27/09/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Hansen, S

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/ZA 01/00013

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5425747	A	20-06-1995	US 5584859 A	17-12-1996
US 5584859	A	17-12-1996	US 5425747 A	20-06-1995
US 5843125	A	01-12-1998	NONE	
US 5047047	A	10-09-1991	US 4924866 A	15-05-1990
			AU 4502489 A	14-05-1990
			CA 2001545 A1	26-04-1990
			KR 9305912 B1	29-06-1993
			WO 9004356 A1	03-05-1990